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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,331

11/17/2003

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EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

03/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/715,331	LAKNER ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-13 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) 18-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-13, 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment filed on December 28, 2007.

Claims 2-13 and 17-29 are pending in this application.

Election/Restrictions

Claims 18-29 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on April 16, 2007.

In response to the election of a single compound (or a set of compounds), applicant elected “the lipoasparagine compound with a linear hydrocarbon as the R¹ group and a linear hydrocarbon as the R² group and CH₂ as the X group”.

A compound falling within the elected set of compounds as indicated in the response was not found in the prior art search and the search was **expanded** to the subgenus of ‘the lipoasparagine compounds with **a linear or branched hydrocarbon as the R¹ group and a linear hydrocarbon as the R² group and CH₂ or O as the X group**’, and art was found.

Claims 2-13 and 17 read on the expanded subgenus above.

As per the guidelines of MPEP § 803.02, the Markush-type claims were examined to the extent of the searched subgenus. Claims 2-13 and 17 (**all in part**, drawn to generic subject matter or species **other than** as indicated above for the expanded subgenus, i.e., lipocysteine, liposerine and all other fatty amino acid derivatives; and R¹ and R² are other than a linear hydrocarbon, encompassed by the instant claims) **are withdrawn** from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The following rejections are maintained:

1. Claims 2-13 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a Lipoasparagine (ALP) compounds (having the formula as depicted in claim 2), does not reasonably provide enablement for fatty amino acid compounds of the instant claims generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The reasons provided in the previous office action are incorporated herein by reference (the reasons are provided below for convenience):

The specification fails to enable the preparation of the entire scope of the claimed compounds. The process scheme I in the specification provide the essential starting materials to prepare the claimed Lipoasparagine (ALP) compounds wherein R^1 and R^2 are each a linear hydrocarbon, however, there is no disclosure of the sources of starting materials needed to prepare the other fatty amino acid derivatives encompassed by the instant claims. Further, the definition of the terms R^1 and R^2 include '**a cholesterol moiety, a steroid moiety, an aromatic moiety, or a combination thereof**', all of which encompass a large number of groups for which there is insufficient evidence of enablement in the specification. The specification provides processes of preparing the Lipoasparagine of the formula disclosed in claim 2 wherein both R^1 and R^2 represent a linear hydrocarbon, however, does not provide any explanation of what other types of compounds are intended by the instant recited "fatty amino acid derivatives"; or sources of starting materials required to prepare all types of compounds falling within the scope of the instant claims, such that a person of ordinary skill could determine if a particular compound is suitable to be a 'fatty amino acid compound' as recited in the instant claims.

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The specification provides the preparation of a specific type of 'asparagine compound' (i.e., a perhydropyrimidinone compound) by cyclizing asparagine with an aldehyde R^1CHO and reacting with an acid chloride R^2XCOCI , however, does not provide any explanation or sources involved to prepare all other types of 'fatty amino acid derivatives' of the instant claims, such that a person of ordinary skill could determine if a particular group is suitable to be a 'fatty amino acid compounds' intended by the instant claims. The instant claims encompass all types of compounds, i.e., cyclic, acyclic, etc. and the specification does not enable the preparation of all types of compounds of the instant claims. It is known that a molecule containing both amine and a carboxyl functional group represents an amino acid, however, the specification does not provide sufficient guidance as to what is encompassed by the recitation of 'fatty amino acid derivative' in the claim, such that one of ordinary skill in the art could prepare the claimed compounds for the use disclosed in the specification, without having burdensome undue experimentation.

In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention. The starting material sources necessary to obtain the instant compounds must have been available as of the filing date in order to provide an enabling disclosure. See *In re Howarth*, 654 F.2d 103, 210 USPQ 689 (CCPA 1981); *Ex parte Moersch*, 104 USPQ 122 (POBA 1954). Applicants should show that the sources of these starting materials was common knowledge or readily available at the time of filing.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant submits that 'the rejection is moot in view of the pending claims'.

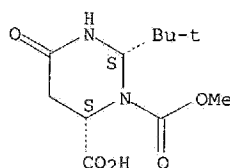
However, the claims continue to recite the terms '**a cholesterol moiety, a steroid moiety, an aromatic moiety, or a combination thereof**' in the definitions of R^1 and R^2 , which include all types of 'moieties' and there is no explanation or sources involved to prepare all the types of compounds wherein R^1 and R^2 are any of these moieties. The specification neither provides appropriate synthetic procedures showing the starting compounds required for the preparation of these types of compounds; nor there are examples illustrating the above terms in the compounds.

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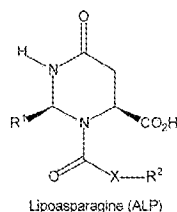
2. Claims 2, 4, 11 and 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al. (J. Am. Chem. Soc. 1992). The instant claims read on reference disclosed compounds, see the compounds 6 and 7 in page 1801.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the reference does not describe each and every element of the pending claims'. Specifically applicant indicates that: 'the R² group of structure in claim [1] 2 is selected from a linear, branched, saturated and/or unsaturated hydrocarbon; ...'.

The reference disclosed compound 7 has the following structural formula:



The compound represents the lipoasparagine (ALP) compound having the formula:



wherein:

R¹ is t-butyl (i.e., -C(CH₃)₃) or a branched hydrocarbon having 4 carbon atoms);

X is O; and

R² is methyl (i.e., -CH₃ or a linear hydrocarbon having 1 carbon atom).

As can be seen from the above, the reference discloses a compound containing a hydrocarbon group in place of the R² group.

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3. Claims 2-7, 11 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (JACS 1992). The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'Chu et al. does not teach all limitations of the currently pending claims'. This is not found to be persuasive. As explained under the 102 rejection above, the reference disclosed compound falls within the instantly claimed genus of claim 2; claims 3 and 5 are drawn to structural analogs of the reference disclosed compounds as these claims recite: 'wherein R¹ and R² are same' and 'at least one of R¹ and R² is a hydrocarbon of at least 5 carbon units' respectively.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/Deepak Rao/
Primary Examiner
Art Unit 1624**

March 21, 2008